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SERIAL NUMBER FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. 08/922,263 09/02/97 CROWLEY BSC011 **EXAMINER** QM22/1027 TESTA HURWITZ & THIBEAULT SHAY, D HIGH STREET TOWER ART UNIT PAPER NUMBER 125 HIGH STREET BOSTON MA 02110 3739 10/27/00 DATE MAILED: This is a communication from the examiner in charge of your application. COMMISSIONER OF PATENTS AND TRADEMARKS Responsive to communication filed on August 15 200 This action is made final. A shortened statutory period for response to this action is set to expire _____ _ month(s), ___ Failure to respond within the period for response will cause the application to become abandoned. THE FOLLOWING ATTACHMENT(8) ARE PART OF THIS ACTION: 1. Notice of References Cited by Examiner, PTO-892. 2. D Notice re Patent Drawing, PTO-948. Notice of Art Cited by Applicant, PTO-1449. 4. Notice of informal Patent Application, Form PTO-152. 6. 🗆 _ 5. Information on How to Effect Drawing Changes, PTO-1474. SUMMARY OF ACTION 1. 1 Claims 1, 3-12, 14-17, 20-30, 32-44, 47-50 52+53 2 D Claims 2,13,18,19,31,45,46, +51 are subject to restriction or election requirement. 7. 🔲 This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes. 8. Formal drawings are required in response to this Office action. 9. The corrected or substitute drawings have been received on _ Under 37 C.F.R. 1.84 these drawings are \square acceptable. \square not acceptable (see explanation or Notice re Patent Drawing, PTO-948). 10.

The proposed additional or substitute sheet(s) of drawings, filed on _ _____ has (have) been 🔲 approved by the examiner. disapproved by the examiner (see explanation). 11.

The proposed drawing correction, filed on _______, has been approved. disapproved (see explanation). 12. Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has Deen received not been received been filed in parent application, serial no. ____: filed on _ 13. Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213. 14. Other

EXAMINER'S ACTION

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16, 17, 20-30, 32-44, 47-50, 52 and 53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 16, 20, 32 and 47 what structure is intended to be indicated by a portion "of variable length" is unclear as this term lacks antecedent basis in the original specification. For the purposes of examination, this term will be interpreted to indicate that the structure can be inserted a varying distance into the body. Also in claim 16 exactly what is to be encompassed by the term "electronically connected" is unclear, as there is no disclosure of any electronics per se in the connection between the energy and the light source. For the purposes of examination, the term will be read as -- electrically connected --.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 16 and 17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had

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possession of the claimed invention. The "X-ray generating light source" is actually the collapsing cavitation bubbles (see Vona et al, page 706, fourth paragraph). Applicant has disclosed no electrical connection to the cavitation bubbles.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 5-8, 10-12, and 15-17 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Takayama et al.

Claim 16 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by Parker et al.

Claims 3, 4, 9, 14, 20-30, 32-44, 47-50, 52, and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takayama et al in combination with Champelon et al ('526).

Takayama et al teach a device as claimed except for the specific recitation that it be placed in the body. Chapelon et al teach the equivalence of applicators for extracorporial and intracorporial use. It would have been obvious to the artisan of ordinary skill to configure the device of Takayama et al for intracorporial use, by employing the pressure wave generator of Champelon et al ('526), since this lends itself to intracorporiae application, as taught by Champlon et al ('526) and to use the particular, pressure generating crystal and various beam directing elements or other housing modifications, since these are well known in the art, as well as to employ any of the other light sources claimed, since these are equivalents and can be used for tissue identification via transmittance, reflectance, fluorescence, or Raman spectra, official of all of the foregoing having already been taken and the notoriousness in the art of the use of such sources

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already officially noticed having been shown by the references already supplied, thus producing a device such as claimed.

Regarding claim 1 applicant appears to be arguing that the recitation in section (iii) should be treated as a means under the sixth paragraph 35 USC 112, however applicant has not employed the proper "means for" language to invoke the sixth paragraph (see OG July 25, 2000). Even of this were language of the proper form, the recitation of the lens is too much structure to support the invocation of the sixth paragraph. However, even assuming, arguendo, that the claims could be construed to claim a lens to the exclusion of all else, the non-planar surface of the water in the device of Takayama is considered to fulfill the recitation. Applicant then argues Takayama does not teach a "sonoluminescent light module" (emphasis in original); further argufing that sonoluminescence refers to luminescence generated by high frequency sound waves, referring to page 12, lines 5-6 of the instant specification; and lastly arguing that Takayama does not describe the production of light by soundwaves. The examiner will address these arguments from last to first. Firstly, under section 102 of the statute, it is not necessary for Takayama to discuss the production of light, it is merely required that light be produced thereby. Beginning at the second column on page 706 of Vona et al, it is clearly stated in the first sentence of the first full paragraph therein that devices such as Takayamas produce sonoluminecence. This is attributed to the "high amplitude pressure fronts" in the first sentence of column 2 on page 706. The abstract of Vona et al notes that the devices have a maximum pressure excusion of 52 Mpa. Since 52 negapascals is equal to a little over 513 atmosphers (1 atmosphere is equal λ

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to 101325 Pascals), the device of Takayama, which produces thousands of atmospheres (see column 7, lines 31-32,) clearly exceeds the pressure threshold for producing sonoluminescence. Since sonoluminescence is clearly produced by the device of Takayama, it clearly constitutes a "sonoluminescent module" within the broadest reasonable interpretation of the term, as applicant has pointed to no structure diffirentiating the Takayama device and a sonoluminescent module, the the assertion that the Takayama device is not a sonoluminescent module, standing alone, is not pursuasive.

Applicant then argues that the housing does not have an optically transparent portion.

The examiner must disagree, as part of the light of produced are x-rays, the housing is clearly transparent to the radiation, and thus is "optically transparent" as the term is broadly construed in light of the specification.

Regarding the Champelon ('526) reference, the examiner respectfully invites applicants attention to column 12, lines 38-47 thereof wherein the "therapy device" as shown in figure 1 and 8 of Champelon, for example, is described as "an intracavity device". The reference to figure 9 pointed to by applicant, is not the teaching upon which the examiner is relying. Since Takayama inherently produces sonoluminescence since neither Takayama nor Champelon lack any feature relied upon by the examiner and since the equivalence of the various light sources has been set forth in the specification and by official notice by the examiner both of which remain undisputed by applicant, the rejections are proper.

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Applicant's arguments filed August 15, 2000 have been fully considered but they are not

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persuasive. .

Applicant's arguments with respect to claims 16 and 17 have been considered but are

moot in view of the new ground(s) of rejection.

Applicant's amendment necessitated the new ground(s) of rejection presented in this

Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE

MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this

final action.

Any inquiry concerning this communication should be directed to David Shay at

telephone number (703) 308-2215.

David Shay:bhw

October 13, 2000

DAVID M. SHAY

PRIMARY EXAMINER

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